New Stannous Fluoride Toothpaste Actively Prevents Dental Plaque Accumulation

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ABSTRACT

Objective: To evaluate the plaque prevention efficacy of new stannous fluoride (SnF) toothpaste (TheraBreath® Healthy Gums) compared to commercial sodium fluoride (NaF) control (Crest® Cavity Protection).

Methodology: A double-blind, randomized, stratified, parallel-design, 2-week clinical study. At each site visit, subjects reported 12 hours after toothbrushing and 4 hours after eating and drinking. Subjects rinsed with a disclosing solution and were evaluated for plaque using the Turesky-Modified-Quigley-Hein Plaque Index. After Day-0 baseline evaluation, subjects underwent dental prophylaxis, followed by 2-minute supervised brushing with their assigned products (TheraBreath, n=47; Crest, n=44). Subjects brushed in the evening and returned the next day (Day 1) for assessment of overnight (12-hour) plaque buildup. Subjects then brushed twice daily for 2 minutes with their assigned products. On Day 14, subjects were re-assessed for overnight plaque levels.

Day-14 subject-wise whole-mouth plaque scores were the primary endpoint for treatment comparisons; Day-1 scores and scores from specific mouth subsets were secondary end points. Statistical analyses employed analysis of covariance with baseline scores as covariable for treatment comparisons. Within-treatment comparisons of mean baseline to pre-brushing scores were conducted using paired t-tests; between-treatment comparisons were calculated as ratios and percentages. All statistical tests were two-sided (α=0.05).

Results: Both toothpastes significantly ($p<0.001$) reduced whole-mouth plaque regrowth after 1-day and 14-day use. TheraBreath toothpaste was significantly ($p<0.001$) more effective than Crest toothpaste. The whole-mouth plaque score for TheraBreath toothpaste was 65% lower than for Crest on Day 1 and 32% lower on Day 14; whereas scores in hard-to-reach sites were 60–64% lower after 1 day and 23–32% lower after 14 days.

Conclusion: TheraBreath® Healthy Gums toothpaste prevents plaque accumulation significantly more effectively than Crest® Cavity Protection toothpaste.

METHODS

This IRB-approved, randomized, double-blind, parallel study used Soparkar Modification of Turesky Modification of the Quigley Hein Plaque Index[1-3] (PI) to assess the plaque prevention potential of two dentifrices over a 14-day test period.

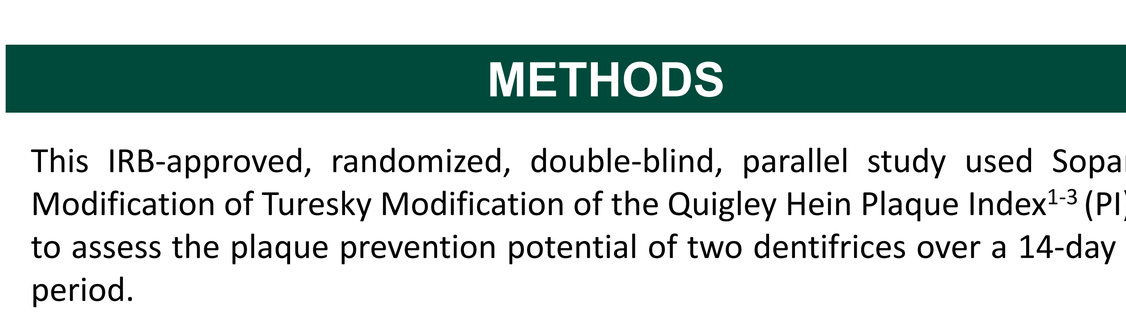
Key Inclusion Criteria:

- ≥18 years of age; generally healthy
- Sufficient maxillary dentition (≥18 teeth) with scorable facial and lingual surfaces
- Mean full-mouth pre-bushing plaque score of ≥2.00 at baseline evaluation
- No advanced periodontal disease, oral pathology, or untreated caries

Treatment Groups:

- Regular dentifrice: 0.243% NaF (Crest® Cavity Protection)
- Test dentifrice: 0.454% SnF (TheraBreath® Healthy Gums)

Figure 1. Consort Diagram Showing Overall Study Flow



Key Study Elements:

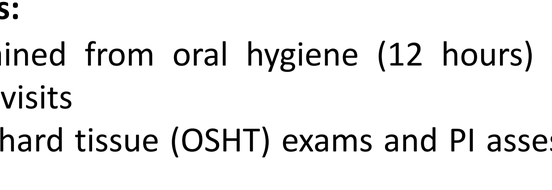
- Subjects refrained from oral hygiene (12 hours) and food/drinking (4 hours) before visits
- Oral soft and hard tissue (OSHT) exams and PI assessments on Days 0, 1, and 14
- Day 0 included dental prophylaxis and supervised 2-minute brushing with assigned dentifrice and toothbrush (Oral-B 35, soft, flat trim; Procter & Gamble, Cincinnati, OH); subjects brushed twice daily at home thereafter
- Compliance verified by supervised brushing, diaries, and toothpaste tubes weighing

Clinical Scoring:

- All PI assessments done by the same examiner
- Plaque scored using the PI 0–5 scale[1-3]

Statistical Methods:

- ~45 subjects per group provided 80% power to detect a 10% between-group difference (α=0.05)
- Primary endpoint: Day-14 whole-mouth PI scores
- Secondary endpoints: Day-1 whole-mouth PI scores; Day-1 and Day-14 hard-to-reach PI scores
- ANCOVA with baseline PI scores as a covariate



RESULTS

Demographics:

- Ninety-one subjects were screened, randomized, and completed all phases of the study. The two treatment groups showed no statistically significant differences with respect to age and gender
- Crest® Cavity Protection (n=44): participants had a mean age of 47.3 ± 12.6 years (range 25–69); sex: 75% female, 25% male
- TheraBreath® Healthy Gums (n=47): participants had a mean age of 44.9±13.6 years (range 19–68); sex: 81% female, 19% male

Safety:

No adverse events were observed.

Efficacy:

- TheraBreath exhibited statistically significant ($p<0.0001$) whole-mouth plaque prevention efficacy with reductions of 65% on Day 1 and 32% on Day 14 relative to the control. See Fig. 2
- TheraBreath exhibited statistically significant ($p<0.0001$) plaque prevention efficacy in hard-to-reach areas with reductions of 60%–64% on Day 1 and 23%–32% on Day 14 relative to the control. See Fig. 3

Fig. 2 Whole-Mouth Plaque Results

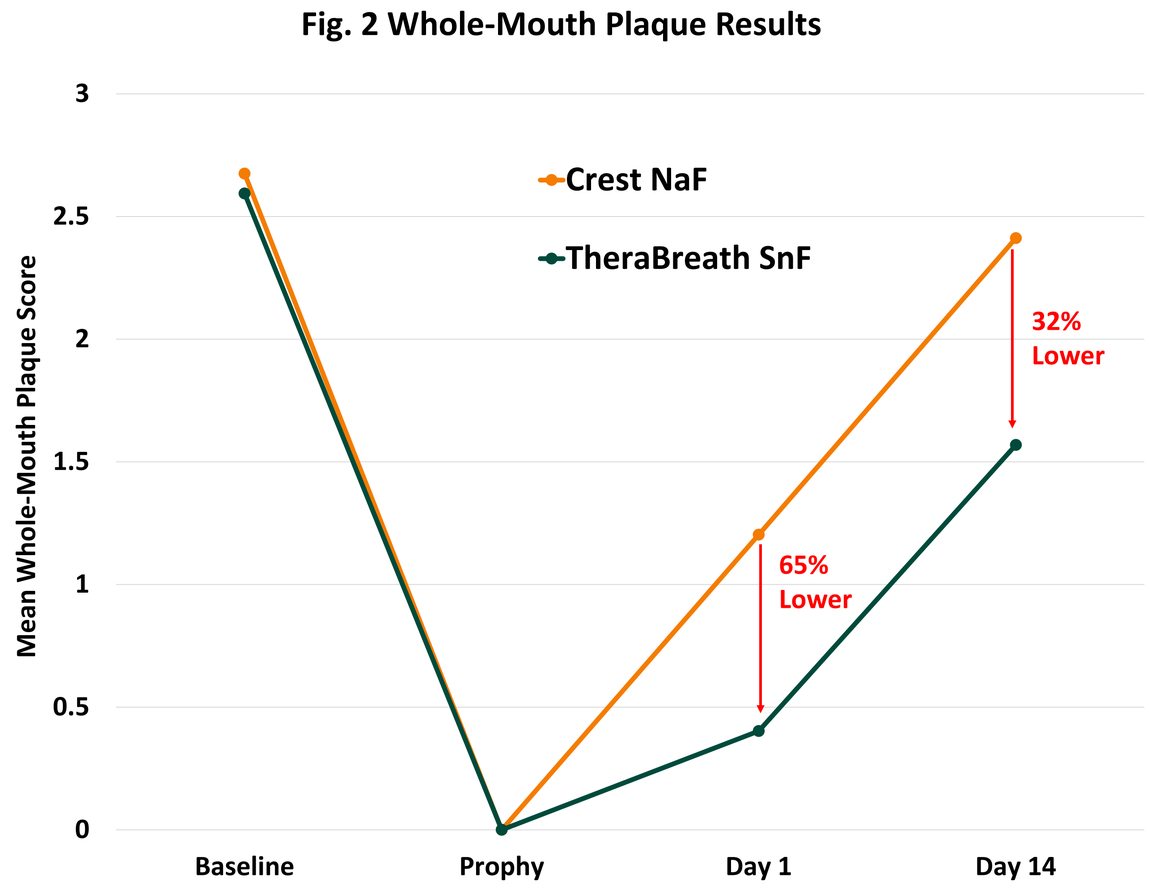
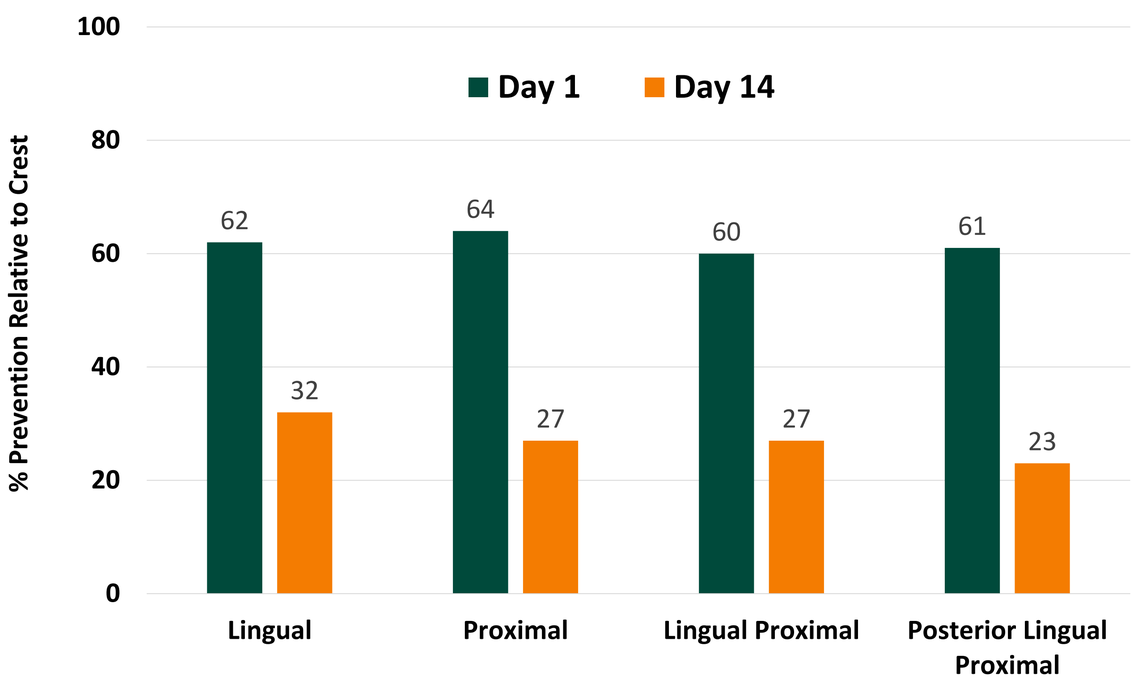


Fig. 3 Hard-To-Reach Areas Comparison



CONCLUSIONS

A new toothpaste with SnF, TheraBreath® Healthy Gums, prevents dental plaque buildup following a professional dental prophylaxis significantly more effectively than a regular NaF toothpaste, Crest® Cavity Protection.

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